

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

# ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

1. REGISTRATION NO. 74-R-0106	CUSTOMER NO. 9464	FORM APPROVED OMB NO. 0579-0036
2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code) AMERICAN ANIMAL HEALTH, INC. 2619 SKYWAY DRIVE GRAND PRAIRIE, TX 75052 (972) 641-5420		

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

## FACILITY LOCATIONS(sites)

See Attached Listing

## REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS  (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-Human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
Cattle	0	11	0	63	74
13. Other Animals					
Goat	0	955	0	0	955

## ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

## CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SI	ICIAL (Type or Print)	DATE SIGNED 10/9/06
PART 1 - HEADQUARTERS		

(b)(6), (b)(7)c

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## II. Column E explanations:

Requalification of a new reference bacterin every two years is required by the USDA for a licensed product. For this purpose, our firm conducted the re-qualification host animal immunogenicity test for each of the following two products: (1) Mannheimia Haemolytica-Pasteurella Multocida Bacterin, Code 7935.01. (2) Mycoplasma Bovis Bacterin, Code 2760.00. Each required using 18 susceptible animals, i.e. 10 vaccinate, 5 placebos, and 3 environmental control. These tests were accomplished by the challenge-protection evaluation, which invariably subjected animals to pain or distress in order to determine its effect on reduction of clinical symptoms for product efficacy. At the end of the experiment, animals were euthanized by captive bolt stunning followed by exsanguinations and necropsy. The pivotal evaluation is based on lung lesion sores. Treatment of animals after challenge would interfere demonstration of product efficacy and performance. There were no coded requirements for this by the USDA.

We also conducted a host animal immunogenicity test using 38 susceptible calves, i.e. 22 vaccinates, 11 placebos, 5 environmental control for the licensing application of Mycoplasma Bovis Bacterin, Code 2700.01. Its evaluation was same as the procedure presented in the above requalification.

In all, there were a total of 11 environmental controls, that were not challenged. The remainder of 63 animals consisting of vaccinates and placebos were challenged and in the category of column E.

(b)(6), (b)(7)c

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